

Remarks

Prior to this amendment, claims 5-15, 18-21, 25-31, 33-41, 43-46, 49-53, 59, 61-65, 68-69, 72, and 74-77 were pending (of which claims 7, 14, 28-31, 33-41, 43-46, 49-53, 59, and 61-64 were withdrawn). New claims 78-82 are added and claims 50-53, 61-64, 72, and 77 are deleted herein. Claims 5-8, 15, 25, 26, 44, 65, and 76 are amended herein.

Claims 5-6, 8, 25, 65, and 76 are amended to correct matters of form. Claim 7 is amended to be in independent form. Withdrawn claim 44 is amended to parallel the scope of the examined claims. Support for the amendment of claim 15 can be found in the specification at least at page 16, lines 20-21, and in original claim 72. Support for the amendment of claim 26 can be found in the specification at least at page 14, line 25 through page 15, line 29.

No new matter is introduced by the foregoing amendments. After entry of this amendment, claims 5-15, 18-21, 25-31, 33-41, 43-46, 49, 59, 65, 68-69, 74-76 and 78-82 are pending (of which claims 28-31, 33-41, 43-46, 49, and 59 continue to be withdrawn). Consideration and allowance of the pending claims are requested.

Examiner Interview

Applicants thank Examiner Nguyen for the courtesy of the October 21, 2010 telephonic interview with their representative, Dr. Anne Carlson, during which the rejections of the claims were discussed. Applicants believe that the claims as amended are in accordance with the Examiner's suggestions and are in condition for allowance.

Withdrawal of Finality of Previous Office Action/Rejoinder of Claims

Applicants thank Examiner Nguyen for withdrawing the finality of the Office action issued on April 24, 2009, and for acknowledging the submission on October 22, 2009 of the Request for Continued Examination and the submission on February 3, 2010 of the Response to Notice of Non-Compliant Amendment. Applicants also thank Examiner Nguyen for rejoining claims 7 and 14.

Allowable Subject Matter

Applicants thank Examiner Nguyen for stating that claims 18 and 74-75 are allowable.

Claim Objections

Claim 7 is objected to as allegedly being an improper dependent claim for failing to further limit the subject matter of a previous claim. Applicants respectfully disagree. However, solely to advance prosecution in this case, claim 7 is amended to be in independent form.

Claim 77 is objected to as allegedly being a substantial duplicate of claim 74. Claim 77 is canceled, rendering the rejection of this claim moot.

In view of the above discussion and amendments to the claims, Applicants respectfully request that the objections of claims 7 and 77 be withdrawn.

*Claim Rejections Under 35 §U.S.C. 102(e)*Venter *et al.* (U.S. Patent No. 6,812,339)

Claims 5-9, 11-14, 25-26, 65, and 68-69 are rejected under 35 §U.S.C. 102(e) as allegedly anticipated by Venter *et al.* (U. S. Patent No. 6,812,339) because limitations such as “an amino acid sequence at least 99% identical to SEQ ID NO: 8” and “nucleic acid sequence is at least 95% identical to SEQ ID NO: 37” are not “necessarily limited to a comparison between an amino acid sequence or a nucleic acid sequence over a full-length SEQ ID NO: 8 (reference sequence) and a full-length SEQ ID NO: 37 (reference sequence), respectively” (Office action at page 4). Applicants respectfully disagree. However, solely to advance prosecution in this case, claims 5-8, 25, and 65 are amended to recite “the amino acid sequence of SEQ ID NO: 8” (claims 5, 25, 65, and 76), “the nucleic acid sequence of SEQ ID NO: 37” (claims 6 and 8), or “the nucleic acid sequence of SEQ ID NO: 37, SEQ ID NO: 38 or SEQ ID NO: 39” (claim 7), thereby referring to the full length sequence, as suggested by the Examiner at page 7 of the Office action and during the telephone interview.

The nucleic acid sequence SEQ ID NO: 416 of Venter *et al.* is 100% identical to nucleotides 43-1563 of SEQ ID NO: 37, but is only 72.3% identical across the full-length of

SEQ ID NO: 37 (which is 2208 nucleotides in length). As claims 5-8 are amended to refer to the full-length SEQ ID NO: 8 (claim 5) or SEQ ID NO: 37 (claims 6-8), claims 5-8, as amended, are not anticipated by Venter *et al.* Claims 9, 11-14, 65, and 68-69 depend, directly or indirectly, from amended claim 5 and incorporate all the limitations thereof. In view of the amendments to the claims, Applicants respectfully request that this rejection of claims 5-9, 11-14, 25, 65, and 68-69 be withdrawn.

Claim 26 is rejected because allegedly there is “no requirement whatsoever that a nucleic acid molecule in a composition of claim 26 has to have any of nucleotides 1-42 of SEQ ID NO: 37” (Office action at page 5). Applicants disagree. However, solely to advance prosecution in this case, claim 26 is amended to recite that “the nucleic acid molecule comprises at least 20 contiguous nucleotides of nucleotides 1-42 of SEQ ID NO: 37, SEQ ID NO: 38, or SEQ ID NO: 39 and encodes a RFX4_v3 polypeptide at least 99% identical to the amino acid sequence of SEQ ID NO: 8, SEQ ID NO: 6, or SEQ ID NO: 10, respectively.” In view of the amendment of claim 26, Applicants respectfully submit that this claim is not anticipated by Venter *et al.* and request that this rejection be withdrawn.

GenBank Accession No. BB611282.1

Claims 5-8, 11, 14-15, 19, 26-27, 65, 68-69, 72, and 76 are rejected under 35 §U.S.C. 102(e) as allegedly anticipated by GenBank Accession No. BB611282.1 (October 26, 2001) because it “has at least nucleotide residues 432-473 that are identical to nucleotides 1-42 of SEQ ID NO: 37” (Office action at page 6). Applicants respectfully disagree with this rejection.

SEQ ID NO: 37 is 2208 nucleotides long and Accession No. BB611282.1 is 591 nucleotides long. An alignment of Applicants’ SEQ ID NO: 37 and Accession No. BB611282.1 using NCBI BLAST analysis confirms that there is 100% identity between these two sequences, but only over a stretch of 68 nucleotides (which includes nucleotides 1-42 of SEQ ID NO: 37). However, the percent identity between these sequences drops to 95% when the alignment is extended over another 62 nucleotides (**Exhibit A**). No other areas of significant homology between these sequences were identified in this alignment.

Thus, although Accession No. BB611282.1 is a nucleic acid sequence that includes nucleotides 1-42 of SEQ ID NO: 37, it is not (i) an isolated nucleic acid sequence at least 95% identical over the full length of the nucleic acid sequence of SEQ ID NO: 37 (claims 6 and 7); (ii) an isolated nucleic acid molecule comprising at least 20 contiguous nucleotides of nucleotides 1-42 of SEQ ID NO:37, wherein the isolated nucleic acid molecule encodes a RFX4_v3 polypeptide at least 99% identical over the full length of the amino acid sequence of SEQ ID NO: 8 (claim 15); nor does it (iii) encode an amino acid sequence at least 95% identical over the full length of the amino acid sequence of SEQ ID NO: 8, wherein fourteen consecutive amino acids within the N-terminal sequence of the polypeptide are identical to residues 1-14 of SEQ ID NO: 8 (claim 5), as required by the current claims. Thus, GenBank Accession No. BB611282.1 does not and cannot anticipate claims 5, 6, 7, or 15, or claims 8, 11, 14, 19, 26-27, 65, 68, 69, 72, and 76 which depend therefrom. In view of the above discussion and the amendments to the claims, Applicants respectfully request withdrawal of this rejection.

Andersen *et al.* (U.S. Patent No. 7,560,542)

Claims 15, 19-21, and 26-27 are rejected under 35 §U.S.C. 102(e) as allegedly anticipated by Andersen *et al.* (U.S. Patent No. 7,560,542) because it discloses “an isolated nucleic acid molecule comprising SEQ ID NO: 65,529 which is a 386 nucleotide molecule that has nucleotides 129-144 that are identical to nucleotides 16-31 of SEQ ID NO: 37” (Office action at page 6). Applicants respectfully disagree. However, solely to advance prosecution in this case, claim 15 is amended to incorporate the limitation of dependent claim 72 (not included in this rejection) into claim 15. Claim 15, as amended, is directed to “at least 20 contiguous nucleotides of nucleotides 1-42 of SEQ ID NO: 37, SEQ ID NO: 38, or SEQ ID NO: 39.” As SEQ ID NO: 65,529 of Andersen *et al.* has identity to SEQ ID NO: 37 across only 16 contiguous nucleotides, claim 15, as amended is distinguishable from Anderson *et al.* Claims 19-21 and 26-27 depend, directly or indirectly, from amended claim 15 and incorporate all the limitations thereof. In view of the amendment to claim 15, Applicants respectfully submit that Andersen *et al.* does not and cannot anticipate claims 15, 19-21 and 26-27, as amended, and request that this rejection be withdrawn.

The claims are not obvious in view of the cited references

Applicants respectfully submit that claims 5-9, 11-15, 19-21, 25-27, 65, 68-69, 72 and 76 are also non-obvious in view of the cited references. As discussed above, none of Venter *et al.*, GenBank Accession No. BB611282.1, or Andersen *et al.* disclose the claimed isolated nucleic acid sequences or methods of using them. In addition, the cited references do not disclose polypeptides having RFX4_v3 activity. As the references do not teach all of the elements recited in the claims, there can be no *prima facie* obviousness of the claims. In addition, there is no teaching in these references, either alone or in combination, that would have led one of skill in the art to predict the claimed nucleic acid sequences having RFX4_v3 activity. Thus, Applicants respectfully submit that claims 5-9, 11-15, 19-21, 25-27, 65, 68-69, 72 and 76 are not obvious

Request for Rejoinder

The Examiner has required a restriction between product and process claims. The Applicants have elected claims to a specific product. In accordance with M.P.E.P. § 821.04, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. Applicants expressly request that the method claims be rejoined and the claims examined, at the latest upon the allowance of any of the product claims. It is believed that this is in accordance with the current Patent and Trademark Office Guidelines for Restriction Requirements in TC1600.

The Examiner has also required an election of species, and Applicants elected (a) SEQ ID NO: 37 (encoding SEQ ID NO: 8), (b) SEQ ID NO: 11, and (c) SEQ ID NOs: 33 and 34. It is Applicants' understanding, under the terms of the election of species, that once it is determined that the claims contain allowable subject matter, the search should be extended to the unelected species.

Conclusion

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If any matters remain to be addressed before a Notice of Allowance is issued, the Examiner is formally requested to contact the undersigned prior to issuance of the next Office action, in order to arrange a telephonic interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution.

Respectfully submitted,

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